

20. The oil in water microemulsion of claim 15, wherein said oil concentration varies from 5 to 15 %, weight by weight of said microemulsion (w/wf). --

REMARKS

This Reply is in response to the Office Action dated October 4, 2002 ("Office Action"). The Reply is filed along with a petition fee for a two (2) month extension of time and authorization to charge the required statutory extension fee to deposit account No. 59-0951. A Petition to change order in which Inventors' names appear under 37 C.F.R. 1.182 is also provided herein.

Claims 1-18 were pending in the application at the time of the Office Action and all claims were rejected. In this Reply, Applicants have amended claims 1-3, 5, 6, and 11-18, cancelled claims 7-9, and have added claims 19 and 20. A Marked-Up Version To Show Claim Amendments using standard underlining and bracketing format to highlight the changes made is attached herein. No new matter is presented.

Claim 14 was rejected under 35 U.S.C. §112 and 35 U.S.C. §101 based on a determination that "the claim does not set forth any steps involved in the method/process, it is unclear what method/process Applicant is intending to encompass." In response, Applicants have amended claim 14 to now be a claim dependent on claim 12. Claim 12 has been amended to now directly recite a method of using a Neem Oil microemulsion including providing the same Neem Oil microemulsion that is recited in amended claim 1, and using the same, where the use is selected from the group of uses consisting of cosmetics, toiletries, paints, varnishes, agrochemicals,

medicines and pesticides. Accordingly, the above rejections regarding claim 14 are now both overcome.

Claims 1-13 and 15-18 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention because water was not recited in the body of the claims. In response, these claims have been amended to now explicitly recite water in the body of the claims. Claims 3, 10 and 11 have also been amended to overcome the respective 35 U.S.C. §112, second paragraph rejections. Accordingly, all 35 U.S.C. §112, second paragraph rejections are now overcome.

Turning to rejections based on art, claims 1, 3, 13, 15 and 17-18 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,792,465 to Hagarty. Claims 1-8, 10, 12-13 and 15-16 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,374,614 to Behan et al. ("Behan"). Claims 1-2, 4-5, 10-11, 13 and 15-16 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,045,816 to Narayanan et al. ("Narayanan"). Claim 9 was rejected under 35 U.S.C. §103(a) as being unpatentable over Behan.

Before reviewing the cited art, Applicants will first review the claimed invention as now recited in amended claim 1. Amended claim 1 recites a method of forming an oil in water microemulsion, comprising providing water, at least one surfactant selected from the group consisting of non-ionic alkyl phenol ethoxylated surfactants, and at least one oil selected from the group consisting of Neem Oil and vegetable oils. Neem oil and vegetable oils (e.g. soybean oil) are oils which have significant polarity as compared to other oil types (e.g. mineral oil). These components are mixed and a thermodynamically

stable oil-in-water microemulsion comprising a plurality of droplets of the oil in water is formed. The microemulsion is primary short chain (C_1 to C_6) alcohol-free, ionic cosurfactant-free, and stable upon dilution. Specification support for the claimed microemulsion being primary short chain (C_1 to C_6) alcohol-free can be found on page 9, lines 16-18, for example.

The claimed invention represents the first primary short chain (C_1 to C_6) alcohol-free and ionic cosurfactant-free microemulsion of Neem oil and similar oils. In contrast, known Neem Oil microemulsions require a mixture of surfactants (generally including at least one ionic surfactant) as well as the addition of a primary short chain (C_1 to C_6) alcohol. Being primary short chain (C_1 to C_6) alcohol-free and ionic cosurfactant-free, the claimed microemulsion is safer and more environmental friendly and pharmaceutically acceptable as compared to known microemulsions having Neem Oil as an ingredient.

Claim 2 recites a preferred embodiment of the invention, that being use of only a single surfactant. As defined in the specification on page 9, lines 9-15 the phrase "single surfactant" refers to:

one or more of a plurality of species contained within a designated class of surfactant. For example, if the designated class of surfactant is alkyl phenol ethoxylates, wherein the alkyl group has 8 to 12 carbons, a surfactant containing octyl phenyl ethoxylates or nonyl phenol ethoxylates is considered herein to constitute a single surfactant.

Applicants note that for a given oil and water mixture, most surfactants do not produce microemulsions unless short chain alcohols or ionic surfactants are included, since they are not otherwise thermodynamically stable. Only a surfactant having an appropriate molecular structure, hydrophilic-lipophilic balance (HLB), appropriate partition

coefficient of surfactant of oil and water, and ability to produce ultra-low interfacial tension (e.g. 10^{-3} nN/m) between the phases can permit formation of an oil-in-water microemulsion.

Extensive research was required to find an appropriate surfactant for Neem Oil-in-water (and similar oils such as vegetable oil) microemulsions without the need for primary short chain (C_1 to C_6) alcohols or ionic surfactants. This research led the inventors to discover the class of alkyl phenol ethoxylated surfactants (e.g. nonylphenol ethoxylate), which are non-ionic surfactants.

Returning to the cited art, Hagarty discloses microemulsions that contain insecticides or other insect control agents, and methods for their use. The microemulsions have above 20% hydrocarbon, and use below 7.5% emulsifier. They can be delivered in aerosol form using a hydrocarbon propellant. A phenol sanitizer can also be included.

Although Hagarty mentions Neem Oil as one of the listed insecticides, Hagarty does not disclose any single surfactant microemulsion formulation for any oil. Rather, Hagarty consistently teaches the use of a complex mixed surfactant system comprising two or more surfactants, such as anionic and nonionic surfactants. For example, col. 2., lines 40-53 recite the following:

Surfactants can be cationic, anionic, amphoteric and nonionic surfactants. However, I prefer to use a mixture of an anionic surfactant and a nonionic surfactant. See generally EP677,579.

Especially preferred is an essentially equal mix of isopropylamine sulfonate (Calimulse PRS; Pilot Chemical) and a tristyrlyphenol, such as tristyrlyphenol ethoxylate (Soprophor BSU; Rhone Poulenc). Other suitable nonionic surfactants are Soprophors 4D 384 and FL, and polyethoxylates derived from primary and secondary aliphatic alcohols

having from 8 to 24 carbons atoms in the alcohol alkyl chain. In addition, part or all of the ethylene oxide may be replaced by propylene oxide.

Moreover, Hagarty's mixture also includes at least one primary alcohol which is used as a co-surfactant. For example, col. 3, line 49-59 discloses the following:

In order to achieve acceptable performance at very low emulsifier levels, co-solvent alcohols are also preferably used. Preferably, a mixture of primary organic alcohols are added. One can be a primary aliphatic alcohol having a carbon content of between 3 and 12 carbons (e.g. 1-octanol, 1-hexanol, 1-pentanol, or 1-butanol). The other can be a non-aromatic ether alcohol having less than 20 carbons (e.g. diethylene glycol monohexyl ether, diethylene glycol mono-butyl ether, or propylene glycol mono-butyl ether). Also, certain glycols such as hexylene glycol, triethylene glycol, or 1,4-butanediol can be added.

Hagarty's table appearing at col. 4, line 55 to col. 5 line 15 referred to by the Examiner in the Office Action discloses a complex microemulsion mixture including an anionic surfactant, a non-ionic surfactant, and 1-octanol (which functions as a co-surfactant). The microemulsion does not include Neem Oil or vegetable oil. Since Applicants' claimed microemulsion is ionic cosurfactant-free, and includes Neem Oil or vegetable oil, Applicants submit that amended claim 1 is patentable over Hagarty. Claim 2 which recites the surfactant being a single surfactant adds a further distinction as Hagarty discloses multi-surfactant microemulsions (anionic + nonionic) as noted above.

Behan discloses clear o/w microemulsions comprising a perfume oil, an aqueous phase and one or more surfactants with HLB between 9 and 18, and co-surfactants of which at least 0.5% of ionic co-surfactant. The weight ratio of perfume oil to total surfactant is between 0.85 and 2.5, and preferably above 1. The quantity of perfume oil is 0.01-40% w/w, preferably below 35%, of the microemulsion and the quantity of water

at least 40% w/w, preferably at least 50%. The microemulsions comprise less than 10% preferably less than 5%, of alcohol. The surfactants are preferably of the nonionic type.

Behan does not disclose or suggest the claimed Neem or vegetable oil. As known in the art, each microemulsion composition and process is highly dependent on the particular oil and surfactant(s) used. The perfume oils disclosed by Behan are substantially less polar as compared to the claimed Neem and vegetable oils. Accordingly, it is highly unlikely the teachings of Behan can be used to form Neem Oil microemulsions.

Example 6 was determined by the Examiner to disclose a single ethoxylated surfactant and an oil. Applicants note that the surfactant disclosed by Behan in example 6 is an ethoxylated hydrogenated castor oil. This oil quite different in structure and properties as compared to Applicants' claimed is alkyl phenol ethoxylated surfactant now recited in amended claim 1. Therefore, since both the claimed oil and surfactant recited in amended claim 1 is not disclosed or suggested by Behan, Applicants submit that amended claim 1 is patentable over Behan.

Narayanan discloses a clear, one-phase, efficacious aqueous microemulsion of an agriculturally active pyrethroid insecticide for delivery at a high loading of active is provided herein which is free of nonylphenol ethoxylate. Narayanan does not disclose or suggest the claimed Neem or vegetable oil.

The pyrethroid oils disclosed by Narayanan are substantially less polar as compared to the claimed Neem and vegetable oils. Accordingly, it is highly unlikely the teachings of Narayanan can be used to form Neem Oil microemulsions. The Examiner cites Example 17 as disclosing "an emulsifiable concentrate of a single surfactant

comprising nonylphenol ethoxylate." However, according to col. 11 lines 3-4, the diluted samples all separated into oil and water phases within one half hour. As such, the microemulsion concentrates disclosed in Example 17 does not provide the stability upon dilution recited in amended claim 1. Therefore, Applicants submit that amended claim 1 is patentable over Narayanan.

Amended claim 12 discloses a method of using a Neem Oil microemulsion, and includes the step of providing an oil in water microemulsion including water, at least one surfactant selected from the group consisting of non-ionic alkyl phenol ethoxylated surfactants, and Neem Oil, wherein the microemulsion is primary short chain (C_1 to C_6) alcohol-free, ionic cosurfactant-free and stable upon dilution. This is the same microemulsion recited in amended claim 1. The microemulsion is used for at least one use selected from the group of uses consisting of cosmetics, toiletries, paints, varnishes, agrochemicals, medicines and pesticides. For reasons noted above relative to amended claim 1, Applicants submit that amended claim 12 is patentable over the cited art.

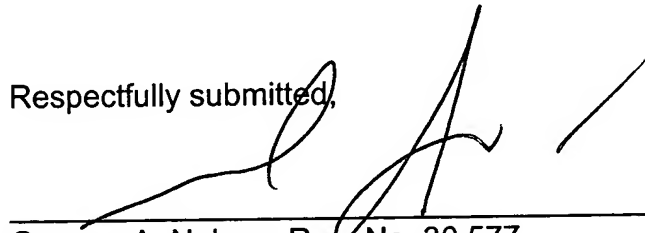
Amended claim 15 recites the microemulsion composition described in amended method claim 1. For reasons noted above relative to amended claims 1, Applicants submit that amended claim 15 is patentable over the cited art.

Applicants have made every effort to present claims which distinguish over the cited art, and it is believed that all pending claims are in condition for allowance. However, Applicants request the Examiner to call the undersigned after review of this

Reply if the Examiner determines that any clarification is necessary to permit issuance of a Notice of Allowance.

Respectfully submitted,

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Marked-Up Version To Show Claims Amendments

IN THE CLAIMS:

1. (Amended) A method of forming an oil in water microemulsion, comprising:

providing water, at least one surfactant selected from the group consisting of non-ionic alkyl phenol ethoxylated surfactants[;providing an], and at least one oil selected from the group consisting of Neem Oil and vegetable oils; and

mixing said surfactant [and], said oil and said water to form an oil-in-water microemulsion, wherein said microemulsion is primary short chain (C₁ to C₆) alcohol-free, ionic cosurfactant-free and stable upon dilution.
2. (Amended) The method of forming an oil in water microemulsion of claim 1, wherein said at least one surfactant [is] consists of a single surfactant.
3. (Amended) The method of forming an oil in water microemulsion of claim 1, wherein said oil varies from 0.001 to 5 % of the oil, weight by weight of said microemulsion [the final product] (w/wf).
4. (Amended) The method of forming an oil in water microemulsion of claim 1, wherein [said surfactant is selected from the group of alkyl phenol ethoxylates, wherein] said alkyl group contains 8 to 12 carbons and said ethoxylate contains an average of 4 to 12 ethoxylate groups.

5. (Amended) The method of forming an oil in water microemulsion of claim 1, wherein said [surfactant is a nonyl phenol ethoxylate] microemulsion is optically clear.

6. (Amended) The method of forming an oil in water microemulsion of claim [1] 2, wherein said [at least one surfactant is a mixed surfactant comprising a nonyl phenol ethoxylate and an ionic surfactant] single surfactant consists of a nonyl phenol ethoxylate.

10. (Amended) The method of forming an oil in water microemulsion of claim 1, wherein said oil concentration varies from 5 to 15 %, w/wf, [whereby] wherein a concentrate of said microemulsion [a concentrate] is formed.

11. (Amended) The method of forming an oil in water microemulsion of claim 10, wherein said surfactant[s] total 15 to 60 % w/wf.

12. (Amended) [The method of forming an oil in water microemulsion of claim 6, wherein said mixed surfactant includes at least one alkyl alcohol having 1 to 7 carbons]

A method of using a Neem Oil microemulsion, comprising the steps of:
providing an oil in water microemulsion including water, at least one surfactant
selected from the group consisting of non-ionic alkyl phenol ethoxylated surfactants,
and Neem Oil, wherein said microemulsion is primary short chain (C₁ to C₆) alcohol-
free, ionic cosurfactant-free and stable upon dilution, and

using said microemulsion for at least one use selected from the group of uses consisting of cosmetics, toiletries, paints, varnishes, agrochemicals, medicines and pesticides.

13. (Amended) [The method of forming an oil in water microemulsion of claim 1, wherein an oil droplet size formed ranges from approximately 5 nm to 80 nm] The method of claim 12, wherein said surfactant consists of a single surfactant.

14. (Amended) [The method of using a microemulsion formed by the method of claim 1, wherein said use is for at least one of the group consisting of cosmetics, toiletries, paints, varnishes, agrochemicals, medicines and pesticides] The method of claim 12, wherein said single surfactant is a nonyl phenol ethoxylate.

15. (Amended) An oil in water microemulsion, comprising:
water;

at least one surfactant selected from the group consisting of non-ionic alkyl phenol ethoxylated surfactants; and

a plurality of oil droplets comprising at least one oil in said water, said oil selected from the group consisting of Neem Oil and vegetable oils, wherein said microemulsion is primary short chain (C₁ to C₆) alcohol-free, ionic cosurfactant-free and stable upon dilution.

16. (Amended) The oil in water microemulsion of claim 15, wherein said at least one surfactant [is] consists of a single surfactant.

17. (Amended) The oil in water microemulsion of claim [15] 16, wherein said single surfactant is a nonyl phenol ethoxylate.

18. (Amended) The oil in water microemulsion of claim [17] 15, wherein said oil comprises Neem Oil [at least one plant includes the Neem Tree].